

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC. and  
BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC. and  
BAXTER HEALTHCARE CORPORATION,

Defendants.

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BAXTER HEALTHCARE CORPORATION,

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC. and  
BAYER HEALTHCARE LLC,

Counterdefendants.

Civil Action No. 05-349-GMS

Jury Trial Demanded

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**MOTION OF DEFENDANTS BAXTER INTERNATIONAL INC. AND BAXTER  
HEALTHCARE CORPORATION FOR RECONSIDERATION OF ORDER GRANTING  
MOTION FOR SUMMARY JUDGMENT THAT THE CLAIMS OF THE '191 PATENT  
ARE NOT INDEFINITE AND OFFER OF PROOF**

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## I. INTRODUCTION

In its June 18, 2007 Order (D.I. 343), the Court granted, *sua sponte*, summary judgment in Plaintiffs' favor on the issue of indefiniteness without considering substantial evidence Baxter Healthcare Corporation and Baxter International Inc. (collectively, "Baxter") would have offered if Plaintiffs had filed a cross-motion for summary judgment. While Baxter believes there was no dispute among the experts that terms such as "acceptable level" were *indefinite* (because none could offer any definition and Plaintiffs' experts conceded they did not know what the term meant), there certainly is a dispute among the experts as to whether that term is *definite*. Though two sides of the same coin, factual disputes may preclude summary judgment of *definiteness* at the same time that there are no disputes of fact to preclude summary judgment of *indefiniteness*.

Baxter needed to go no further in its motion for summary judgment than to Plaintiffs' evidence – especially admissions by Plaintiffs' experts – to show indefiniteness. Likewise, Baxter's experts agreed that "acceptable level" was indefinite. Had Plaintiffs filed a cross-motion that the asserted patent claims were not indefinite -- which they did not do -- Plaintiffs' experts would have had to offer some evidence about what meaning the term "acceptable level" had to skilled artisans. Notably, Plaintiffs did not offer any such definition in response to Baxter's motion for summary judgment. Baxter would have presented evidence about the understanding of skilled artisans as well, including evidence as to the proper test and the corresponding test results for measuring anticomplement activity ("ACA"). In the case of a cross-motion, Plaintiffs' and Baxter's evidence about the meaning of "acceptable level" undoubtedly would have conflicted and a dispute of material fact would have been raised. Summary judgment of *definiteness* would have been precluded by the presence of material issues of fact.

In granting summary judgment in Plaintiffs' favor – a motion that Plaintiffs elected not to file – the Court appears to have adopted Baxter's assertion that there were no disputed material facts as to Baxter's motion for summary judgment. *See* D.I. 343, at 9 ("the court reaches its conclusion having agreed with Baxter that this case does not present any disputes of material fact that affect the legal determination of whether the claims at issue are indefinite"). However, Baxter's acceptance of the testimony of Plaintiffs' experts, and its assertion regarding the absence of disputed facts, was solely for the purposes of its own motion for summary judgment and should not be used against Baxter when ruling on any cross-motion filed by Plaintiffs (if one had been filed) or raised *sua sponte* by the Court. *See* 10A Charles A. Wright, Arthur R. Miller & Mary K. Kane, *Federal Practice and Procedure*, § 2720, at 332-34 (1998) ("It should be remembered that a party moving for summary judgment concedes the absence of a factual issue and the truth of the nonmoving party's allegation only for purposes of his own motion. It follows that ... the assertion that there is no issue of material fact may not be used against the movant when the court rules on his adversary's motion."), attached as Exhibit A to the accompanying Declaration of Anne M. Rogaski in Support of Motion for Reargument ("Rogaski Decl.").

That the asserted claims of the '191 patent are *not indefinite* is a disputed question of fact and should be decided based on a complete factual record. Accordingly, pursuant to Local Rule 7.1.5, Baxter respectfully requests that the Court reconsider its June 18, 2007 Order granting, *sua sponte*, summary judgment that the asserted claims are not indefinite so that Baxter has a full opportunity to present evidence on material factual issues ripe for trial.

## II. LEGAL STANDARD

Delaware Local Rule 7.1.5 permits a party to move for reargument of a Court's order within 10 days after the Court issues its opinion or decision. *See* D. Del. L.R. 7.1.5. While

motions for reargument are to be granted "sparingly" (*id.*), "a court should reconsider a prior decision if it overlooked facts or precedent that reasonably would have altered the result." *Chase Manhattan Bank v. Iridium Africa Corp.*, 2004 WL 1588295, at \*1 (D. Del. July 8, 2004) (granting motion for reconsideration); *Karr v. Castle*, 768 F. Supp. 1087, 1093 (D. Del. 1991) (granting in part motion for reconsideration). Reargument may be granted "to correct manifest errors of law or fact or to present newly discovered evidence," *Harsco v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985), or where "the Court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the Court by the parties, or has made an error not of reasoning but of apprehension." *Brambles USA, Inc. v. Blocker*, 735 F. Supp. 1239, 1241 (D. Del. 1990).

Motions for reargument provide a mechanism to "balance the need for finality in judicial decision making with a recognition that courts sometimes make mistakes." *Karr*, 768 F. Supp. at 1093. In considering a motion for reargument, "the court should keep an open mind, and should not hesitate to grant the motion if necessary to prevent manifest injustice or clear error." *Id.* (citing *Brambles*, 735 F. Supp. at 1240-41). When "the importance of achieving substantial justice outweighs the value of finality," the court should exercise its discretion to reconsider a prior ruling. *Id.* at 1094.

### III. DISCUSSION

Baxter moves for reconsideration on two grounds: (1) it was legally erroneous to rely on Baxter's assertion of an absence of disputed issues on its motion to enter summary judgment against Baxter; and (2) there are numerous disputed facts not considered by the Court that would have precluded any cross-motion for summary judgment that the claims are not indefinite.

**A. Baxter Has Been Unfairly Precluded From Presenting Its Affirmative Evidence Opposing A Cross-Motion for Summary Judgment**

In its June 18 Order, the Court cited the Wright & Miller treatise for the proposition that a court may render summary judgment for the party opposing a summary judgment motion even though that party did not file a cross-motion for summary judgment. *See* Order at 10 (citing 10A Charles A. Wright, Arthur R. Miller & Mary K. Kane, *Federal Practice and Procedure* ["Wright & Miller"], § 2720). Baxter does not disagree with this proposition. However, the treatise states that "great care must be exercised to assure that the original movant [*i.e.*, Baxter] has had an adequate opportunity to show that there is a genuine issue and that the opponent is not entitled to judgment as a matter of law." *Id.*, § 2720, at 352-53 (1998), attached as Ex. A to Rogaski Declaration. The treatise further states:

It should be remembered that a party moving for summary judgment concedes the absence of a factual issue and the truth of the nonmoving party's allegations *only for purpose of his own motion*. It follows that the legal theories the movant advances in support of a Rule 56 motion and the assertion that there is no issue of material fact may *not* be used against the movant when the court rules on his adversary's motion.

*Id.*, § 2720, at 332-34 (emphasis added) (citing numerous authorities).

Here, the Court reached its conclusion that summary judgment against Baxter is warranted on the issue of indefiniteness based, in part, on Baxter's purported concession "that this case does not present any disputes of material fact that affect the legal determination of whether the claims at issue are indefinite." Order at 9 [D.I. 343] (quoting Baxter's Reply Brief at 16); *see also id.* at 11 ("The undisputed facts, viewed as Baxter urges, fail to show that the asserted patent claims are indefinite as a matter of law"). However, Baxter merely indicated that "for purposes of this motion," Baxter would agree that the evidence presented by Plaintiffs was either undisputed or not material. *See* Baxter's Reply Brief (D.I. 242) at 16. Indeed, on the question of *indefiniteness*, the evidence was not in dispute. Had a cross-motion on *definiteness*

been filed, however, there would have been numerous disputed facts on whether “acceptable level” was definite and, if so, what it means. *See* Part III.B *infra*.

The contention by the moving party regarding an absence of disputed facts on its motion for summary judgment is *not* tantamount to a concession there are no issues of material fact had the nonmovant filed a cross-motion. *See* 10A Wright & Miller, § 2720, at 332 (“It should be remembered that a party moving for summary judgment concedes the absence of a factual issue and the truth of the nonmoving party’s allegations only for purposes of his own motion”); *see also Walling v. Richmond Screw Anchor Co.*, 154 F.2d 780, 784 (2d Cir. 1946) (“It does not follow that, merely because each side moves for a summary judgment, there is no issue of material fact. For, although a defendant may, on his own motion, assert that, accepting his legal theory, the facts are undisputed, he may be able and should always be allowed to show that, if plaintiff’s legal theory be adopted, a genuine dispute as to a material fact exists.”).

The Third Circuit recognized this legal point when it quoted with approval a Sixth Circuit decision:

In *Begnaud v. White*, 170 F.2d 323, 327 (6th Cir. 1948), the Court succinctly stated the applicable rule as follows:

The fact that both parties make motions for summary judgment, and each contends in support of his respective motion that no genuine issue of fact exists, does not require the Court to rule that no fact issue exists. Each, in support of his own motion, may be willing to concede certain contentions of his opponent, which concession, however, is only for the purpose of the pending motion. If the motion is overruled, the concession is no longer effective.

Appellants' concession that no genuine issue of fact existed was made in support of its own motion for summary judgment. We do not think that the concession continues over into the Court's separate consideration of appellee's motion for summary judgment in his behalf after appellants' motion was overruled.

*F.A.R. Liquidating Corp. v. Brownell*, 209 F.2d 375, 380 n.4 (3d Cir.1954); *see also Gould v. American Hawaiian S.S. Co.*, 319 F. Supp. 795, 802 (D. Del. 1970) (denying cross-motions for summary judgment on the issue of materiality of misrepresentations in proxy statements).

Therefore, Baxter respectfully submits it was an error to take Baxter's statement of a lack of material facts for its own motion as a concession that no disputes about material facts would exist on a cross-motion, had one been filed. It also was error not to provide Baxter "adequate opportunity to demonstrate why summary judgment [that the claims are not indefinite] should not be granted." *See* 10A Wright & Miller, § 2720 at 339 (emphasis added); *see also Massey v. Del Labs. Inc.*, 118 F.3d 1568, 1573 (Fed. Cir. 1997) ("the separate summary judgment motions in this case do not conclusively show that Massey received a full and fair opportunity to ventilate the issues on which the district court granted judgment"). Accordingly, Baxter requests the Court to reconsider its June 18 Order so that the jury – starting next week – can determine the indefiniteness issue or, alternatively, allow Baxter to demonstrate why a cross-motion for summary judgment for a finding of *definiteness* should not be granted.

**B. Numerous Genuine Issues Of Material Facts Exist As To Whether The Asserted Claims Are Not Indefinite**

In this case, the record was not sufficiently developed to allow entry of summary judgment for the Plaintiffs on the critical issue of indefiniteness. Had Plaintiffs filed a cross-motion for summary judgment that the asserted claims were *definite* as a matter of law, Baxter would have presented evidence showing numerous issues of material fact that would have precluded summary judgment of *definiteness*. These facts were not needed in support of



Baxter's motion, because the undisputed evidence from Plaintiffs' experts showed (in Baxter's opinion) that "acceptable level" was *indefinite*.

For example, there is a clear factual dispute regarding the appropriate test to measure ACA – *i.e.*, hemolytic v. C1q test. This is no trivial matter because the hemolytic test results, as Baxter contends, warrant a finding of noninfringement since they show that ACA levels stay constant or even decrease after solvent/detergent treatment. *See* Rogaski Decl., Exs. B-C. Meanwhile, Plaintiffs contend that the C1q test – which is not a test for ACA – tends to prove infringement since some of the C1q testing of the accused process show increased levels.<sup>1</sup> *See* Rogaski Decl., Ex. D. A fundamental dispute about the proper test to measure ACA – and the fact that the selection of one test tends to show infringement while another demonstrates non-infringement – is compelling evidence of indefiniteness. *See Honeywell Int'l Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1340 (Fed. Cir. 2003) (affirming invalidity determination because the appropriate test for measuring MPE [melting point evaluation] could not be ascertained; hence, the claims were invalid). At the very least, the factual record was not sufficiently developed to permit judgment as a matter of law that the patent claims are *not indefinite*.

There are many other examples of disputed facts that should have precluded summary judgment of *definiteness*. *See* Rogaski Decl., Exs. E-F. That evidence is summarized below:

1. Baxter's invalidity expert, Dr. Thomas Kindt, would testify as to the following issues on indefiniteness:

- there was no single level of acceptability understood by persons of skill in the art at the time the '191 patent application was filed; in fact, there were

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<sup>1</sup> As Baxter will demonstrate at trial, the hemolytic test (and not the C1q test) is the only proper test here; even the '191 patent indicates that ACA levels should be measured by the hemolytic test.



different levels of "acceptability" disclosed in the prior art (*see* Rogaski Decl., ¶ 9);

- the results of tests such as C1q tests cannot be compared to the results of tests used in the prior art to measure ACA "acceptability" because the different assays measure different things – *e.g.*, C1q tests measure C1q binding, which is *not* the same as ACA<sup>2</sup> (*see* Rogaski Decl., ¶ 10);
- ACA tests must be validated for a particular product; in other words, results from validated ACA tests for a particular product cannot be compared to levels of "acceptability" such as those shown in the examples in the '191 patent (*see* Rogaski Decl., ¶ 11);
- if a manufacturer had a product with a known ACA level, comparing its ACA against the prior art would not allow that manufacturer to determine whether or not its ACA level was acceptable (*see* Rogaski Decl., ¶ 12);
- persons of ordinary skill in the art would need identification of the specific test used to measure ACA in order to determine if a product infringes (*see* Rogaski Decl., ¶ 13); and
- a person of ordinary skill in the art would not equate FDA release limits with "acceptable level" as used in the '191 patent (*see* Rogaski Decl., ¶ 14).

2. Documentary evidence that different ACA or complement tests give different results, some of which may appear to fall within the asserted claim and others which do not fall within the claim, including:

- Plaintiffs' C1q and hemolytic tests which give two different results (*compare* Rogaski Decl., Ex. B *with* Ex. D); and
- The Rousell paper which shows that the determination of whether an ACA level is "acceptable" depends upon the parameters of the test that is run (Rogaski Decl., Ex. G).

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<sup>2</sup> Moreover, Plaintiffs never even purport to express what C1q binding level/value is "acceptable" in any of their assertions.

The inability of experts to agree on the meaning of a term would support a finding of *indefiniteness* while at the same time precluding a finding (at least on summary judgment) of *definiteness*. Here, it is entirely plausible – and Baxter contends it is probable – that with this evidence, a reasonable jury would return a verdict in Baxter's favor on the issue of *indefiniteness*. Baxter's assertion that there were no disputed facts on its affirmative motion for summary judgment was not a concession of a lack of material fact as to any cross-motion for summary judgment that Plaintiffs might have – but did not – file. *See, e.g., F.A.R. Liquidating Corp. v. Brownell*, 209 F.2d 375, 380 n.4 (3d Cir. 1954). Rather, it was an acknowledgement of the different question presented by a motion for summary judgment of *indefiniteness* than would be presented by a cross-motion for summary judgment of *definiteness*. Consequently, the Court's *sua sponte* grant of summary judgment is not appropriate.

#### IV. CONCLUSION

Baxter moved for summary judgment that the '191 patent is indefinite on the basis that there were no genuine issues of fact as to *Baxter's* motion. There are ample issues of material fact that Baxter would have presented if Plaintiffs had cross-moved for summary judgment on lack of indefiniteness, which they did not do. Baxter has had no opportunity to show that there are genuine issues that should have prevented summary judgment in Plaintiffs' favor and that Plaintiffs are not entitled to judgment as a matter of law. Baxter should be permitted to present those facts comprehensively at trial. Thus, Baxter respectfully requests the Court to reconsider its prior ruling and reverse its *sua sponte* grant of summary judgment that the claims of the '191 patent are not indefinite.

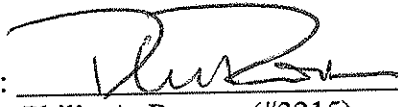
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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Philip A. Rovner, hereby certify that on July 2, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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